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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,882	10/01/2001	Montague Cecil Solomon	6969	7981

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EXAMINER
OH, SIMON J

ART UNIT	PAPER NUMBER
1615	9

DATE MAILED: 04/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/868,882	Applicant(s) SOLOMON ET AL.	
	Examiner Simon J. Oh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's petition for extension of time and the applicant's amendment, both received on 13 January 2003.

Claim Objections

The objection to Claim 6 to under 37 CFR 1.75(c) as being in improper form is rendered moot with the cancellation of that claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite is rendered moot with the cancellation of that claim.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 2, and 7 under 35 U.S.C. 102(b) as being anticipated by Maeda *et al.* is rendered moot with the cancellation of those claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 2, and 7 under 35 U.S.C. 103(a) as being unpatentable over Maeda *et al.* is rendered moot with the cancellation of those claims.

The rejection of Claims 1, 3, 4, and 7 under 35 U.S.C. 103(a) as being unpatentable over Jenkins is rendered moot with the cancellation of those claims.

The rejection of Claims 1-4, and 7 under 35 U.S.C. 103(a) as being unpatentable over Maeda *et al.* and Jenkins and further in view of Hirano *et al.* is rendered moot with the cancellation of those claims.

Claims 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda *et al.* and Jenkins and further in view of Hirano *et al.*

The Maeda *et al.* document discloses a method for the preparation of a pharmaceutical tape composition (See Page 2, Lines 1-5). This preparation involves first adding an alkaline agent to the active substance and optionally dissolving and dispersing the mixture with an organic solvent, and then blending the resulting mixture with an adhesive base (See Page 3, Lines 25-27 and 46-51). Examples of suitable adhesive bases include acrylic resins and silicone rubbers (See Page 2, Line 49 to Page 3, Line 4). Crotamiton is listed as a preferred solvent and may be present in amounts up to 20 parts by weight of solvent to one part of piroxicam, the active substance. Other solubilizing agents that may be used include propylene glycol, ethylene glycol monoethyl ether, and polyethylene glycol (See Page 3, Lines 27-37; and Page 5, Example

2). Manufacturing steps include coating the final pharmaceutical product onto a liner, drying it, and stretching it onto a polyvinyl chloride liner (See Page 3, Lines 49-51; and Examples). Although the method in the Maeda *et al.* document discloses that the piroxicam is first preferably dissolved in an aqueous agent of an alkaline agent, followed by the addition of the organic solvent, the document nevertheless states that the piroxicam/alkaline solution is further dissolved and dispersed into the solvent, which reads on the claims of the instant application.

The Jenkins patent teaches a method of preparing a device for the transdermal administration of a drug (See Abstract). A portion of the preparation process involves dissolving the active ingredient in a solvent mixture and then adding the polymer adhesive solution. The process also includes a step of drying step where the temperature must be at least 100°C. However, lower temperatures may be used for solvents with lower boiling points are used in the preparation process (See Column 2, Line 50 to Column 3, Line 51). Diethyltoluamide (DEET) is listed as a preferred solvent, and several preferred solvent systems are given which comprise diethyltoluamide (See Column 4, Lines 2-21). Oestradiol (estradiol) is given as a possible active ingredient to be included in the transdermal device (See Column 4, Lines 25-26). Example 1 of the patent describes the preparation process where the active ingredient is dissolved by sonication or warming in a solvent system comprising diethyltoluamide, and the resulting mixture is added to an aqueous acrylate adhesive dispersion. Based on the wording of the phrase "a thicker spreading solution" (See Column 6, Lines 40-41) and its context, one of ordinary skill in the art can infer that the resulting mixture of active ingredient, solvent, and adhesive resulted in a solution. Example 2 describes a similar process using oestradiol as the active ingredient. Although the patent discloses that the mixture is then dried into a film in which the active

ingredient exists in a saturated or supersaturated state, it would be obvious to one of ordinary skill that the active ingredient possibly and perhaps likely exists in a state below its saturation point before the drying step occurs.

The Hirano *et al.* patent teaches a percutaneously absorbable patch comprising estrogen and luteal hormones (See Abstract). Estradiol is given as a particular example of an estrogen (See Column 2, Lines 10-14), and it can be present in an amount ranging from 0.01% to 10% of the total weight of the pharmaceutical preparation (See Column 2, Lines 20-23). Crotamiton is discussed as an important component of the preparation, particularly its ability to enhance the active substances, in terms of solubility, release from the preparations, and percutaneous absorption (See Column 2, Lines 46-57).

It would be obvious to one of ordinary skill in the art to combine the teachings of Maeda *et al.*, Jenkins, and Hirano *et al.* into the object of the instant application. Both Maeda *et al.* and Jenkins teach methods of preparing a transdermal composition using steps which read on the claims of the instant application; Maeda *et al.* show methods using crotamiton, while Jenkins *et al.* teach methods using diethyltoluamide and estradiol. Hirano *et al.* teach transdermal compositions comprising estradiol and crotamiton. As discussed above, Jenkins teaches that diethyltoluamide is a preferred component of solvent systems used to prepare transdermal devices, including those comprising estradiol as the active substance. In addition, Hirano *et al.* discloses that solubility, release, and absorption of estradiol can be enhanced with crotamiton. One of ordinary skill would be motivated, with a reasonable expectation of success, to create an estradiol transdermal composition further comprising crotamiton and diethyltoluamide, in order

to take advantage of the beneficial properties of both chemicals combined into a single composition.

Regarding Claim 9 and the broad range of ratios claimed therein, it is the position of the examiner that the contemplation of such a range is one that is easily within the purview of one of ordinary skill in the art. Ratios that fall within the range claimed would be discovered by one of ordinary skill in the art by routine experimentation.

Regarding Claims 15 and 16, no patentable criticality is seen in forming the film on a release liner and then laminating the film onto a backing sheet, or vice versa, above what has been disclosed by Maeda *et al.*

Regarding Claim 17, the use of process temperatures of at least 100°C for the purpose of drying a transdermal composition is specifically disclosed in Jenkins, and the use of process temperatures below 100°C is clearly suggested. This disclosure in Jenkins reads on the claimed range of process temperatures.

Thus, the claimed invention, as a whole, is *prima facie* obvious.

Response to Arguments

The applicant's arguments, received on 13 January 2003, have been considered but are not found to be persuasive.

The applicant asserts an inventive feature as being a stability imparted by a concentration of the active substance below the saturation point in a solvent, for the purpose of preventing crystallization of the active substance during storage. However, no evidence exists on record that demonstrates this particular distinction. In particular, on Page 4 of the present specification,

on the last paragraph, the applicant's disclosure relates the crystallization of the active substance to the ratio of the active substance to the solvent. No data has been presented that establishes ranges of concentrations disclosed in the prior art, such as the presence of a solvent up to about 20 parts by weight per one part of weight of the active substance, as disclosed in Maeda *et al.*, that shows such prior art ranges as not being effective after storage.

The applicant's arguments are based on what the examiner believes to be a narrow interpretation of the prior art. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo
March 27, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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